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| EXAMINER | |
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| CROW, ROBERT THOMAS | |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/586,882 | VAN BEUNINGEN, MARINUS GERARDUS JOHANNE | |
| | Examiner | Art Unit | |
| | Robert T. Crow | 1634 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *02 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) *10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 July 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/20/06; 3/5/07; 4/27/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election without traverse of Group I in the reply filed on 2 December 2008 is acknowledged.

2. Claim 10 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on s December 2008.

3. Claims 1-9 are under prosecution.

### *Preliminary Amendment*

4. The Preliminary Amendment 20 July 2006 is acknowledged and has been entered.

### *Information Disclosure Statement*

5. The Information Disclosure Statements filed 20 July 2006, 5 March 2007, and 27 April 2007 are acknowledged and have been considered.

### *Specification*

6. The use of trademarks (e.g., Sylgard 182, Cy5, Cy3, etc) has been noted in this application. Trademarks should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

### *Claim Rejections - 35 USC § 112*

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 2-5 and 7-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-5 and 7-8 are indefinite in the recitation “said support member” in lines 1-2 of claim 2, line 2 of each of claims 4 and 5, and in the recitation “the support member” in line 2 of each of claims 3 and 7-8. The recitation of “said support member” and “the support member” each lack antecedent basis in the recitation of a “flow through support member” provided in claim 1. It is suggested the phrase “flow through” be added to each recitation to provide proper antecedent basis.

### *Claim Interpretation - 35 USC § 112, Sixth Paragraph*

9. The following is a quotation of the sixth paragraph of 35 U.S.C. 112:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

10. Applicant has invoked 35 USC § 112 Sixth Paragraph in the limitation "means for transporting…sections" in lines 6-7 of claim 9. While the limitations meet the three-prong analysis for consideration under 35 USC § 112 Sixth Paragraph, the limitation "potential means" and the limitation "means for signal detection" are not being treated under 35 USC 112, sixth paragraph because the specification does not provide a limiting definition of the structural elements that define the structures of the means that provide the various functions found in the claims. Thus, the claims are given the broadest reasonable interpretation consistent with the specification (*In re Hyatt*, 211 F.3d1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000) (see MPEP 2111 [R-1]).

***Claim Rejections - 35 USC § 102***

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-4 and 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Stimpson (U.S. Patent No. 6,306,664 B1, issued 23 October 2001).

Regarding claim 1, Stimpson teaches a device for analyzing an interaction between target and probe molecule in the form of Figure 2D, which comprises a tubular housing in the form of sheath 260 (column 6, line 65-column 7, line 10). The housing further comprises a flow through support member in the form of an array comprising through going channels in the form of interstitial spaces 230 (column 6, lines 45-65)

which obstructs the internal passage way of the housing (Figure 2D). The channels are suitable for allowing an interaction between target and probe molecules because probe molecules in the form of binding reagents are impregnated therein (column 6, lines 45-65), wherein the binding reagents are DNA probe molecules (column 9, lines 20-40).

In addition, it is noted that the phrase "suitable for allowing" clearly indicates that the recitation of "an interaction between target and probe molecules" refers to an intended use of the claimed device, and does not actually require target or probe molecules. The courts have held that "while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function." *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). In addition, "[A]pparatus claims cover what a device *is*, not what a device *does*." *Hewlett-Packard Co. v. Bausch &Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original). Therefore, the various uses recited in claim 1 (e.g., allowing an interaction between target and probe molecules) fail to define additional structural elements of the claimed device. Because Stimpson teaches the structural elements of the claim, the claim is anticipated by Stimpson. See MPEP § 2114.

Regarding claim 2, Stimpson teaches the device of claim 1, wherein the support member is provided with probe molecules suitable for interacting with target molecules; namely, the channels comprise probe molecules in the form binding reagents that are impregnated therein (column 6, lines 45-65), wherein the binding reagents are DNA probe molecules (column 9, lines 20-40).

In addition, as noted above, apparatus claims cover what a device *is*, not what a device *does*. The phrase "suitable for interacting" clearly indicates an intended use of the claimed device. Therefore, the various uses recited in claim 2 (e.g., interacting with target molecules) fail to define additional structural elements of the claimed device. Because Stimpson teaches the structural elements of the claim, the claim is anticipated by Stimpson.

Regarding claim 3, Stimpson teaches the device of claim 1, wherein the support member is provide at the distal end of the housing; namely, the support member is places entirely withing the tubular housing (Figures 2D-E); thus, the support member is at the end of the housing.

Regarding claim 4, Stimpson teaches the device of claim 1, wherein the support member (i.e., porous matrix) is an organic polymer; namely, polypropylene (column 3, lines 48-65).

Regarding claim 6, Stimpson teaches the device of claim 1, wherein the channels extend substantially coaxial with the longitudinal axis of the housing (Figures 1B and C).

Regarding claim 7, Stimpson teaches the device of claim 1, wherein the plane of the support member extends substantially perpendicular with the longitudinal axis of the housing (Figures 1B and C).

Regarding claim 8, Stimpson teaches the device of claim 1, wherein the support member spans the bore of the housing; namely, the support member is placed entirely within the tubular housing (Figures 2D-E); thus, the support member is at the end of the housing.

13. Claims 1-5 and 7-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Raybuck et al (U.S. Patent No. 5,556,598, issued 17 September 1996).

Regarding claim 1, Raybuck et al teach a device comprising a tubular housing have a proximal end and a distal end defining an internal flow passageway; namely, Figure 6 shows a tubular housing in the form of pipette tip 10, which is shown having a proximal and distal end (i.e., the ends of the tip; column 8, line 58-column 9, line 55). The housing is further provided with a flow through support member in the form of substrate 17 (column 7, lines 15-30), which obstructs the internal passage way of the housing (Figure 6). Substrate 17 is a membrane that is porous (column 5, lines 30-50), and thus comprises through going channels in accordance with the embodiment described in lines 24-35 on page 6 of the instant specification. Thus, the claim has been given the broadest reasonable interpretation consistent with the teachings of the specification regarding a "channel" (*In re Hyatt*, 211 F.3d1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000) (see MPEP 2111 [R-1]).

In addition, as noted above, it is noted that the phrase "suitable for allowing" clearly indicates that the recitation of "an interaction between target and probe molecules" refers to an intended use of the claimed device, and does not actually require target or probe molecules. As also noted above, apparatus claims cover what a device *is*, not what a device *does*." Therefore, the various uses recited in claim 1 (e.g., allowing an interaction between target and probe molecules) fail to define additional structural elements of the claimed device. Because Raybuck et al teach the structural elements of the claim, the claim is anticipated by Raybuck et al.

Regarding claim 2, Raybuck et al teach the device of claim 1, wherein the support member is provided with probe molecules suitable for interacting with target molecules; namely, capture entities are immobilized on the membrane (column 5, lines 50-60).

In addition, as noted above, apparatus claims cover what a device *is*, not what a device *does*. The phrase "suitable for interacting" clearly indicates an intended use of the claimed device. Therefore, the various uses recited in claim 2 (e.g., interacting with target molecules) fail to define additional structural elements of the claimed device. Because Raybuck et al teach the structural elements of the claim, the claim is anticipated by Raybuck et al.

Regarding claim 3, Raybuck et al teach the device of claim 1, wherein the support member is provided at or near the distal end of the housing (Figure 6).

Regarding claim 4, Raybuck et al teach the device of claim 1, wherein the support member is the organic polymer polyvinylidene difluoride (column 6, lines 1-0).

Regarding claim 5, Raybuck et al teach the device of claim 1, wherein the support member is optically transparent (column 6, lines 10-20).

Regarding claim 7, Raybuck et al teach the device of claim 1, wherein the plane of the support member extends substantially perpendicular with the longitudinal axis of the housing (Figure 6).

Regarding claim 8, Raybuck et al teach the device of claim 1, wherein the support member spans the bore of the housing; namely, the support member is placed

entirely across the opening of tubular housing (Figures 2D-E); thus, the support member is at the end of the housing.

14. Claims 1, 3, and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Fields (U.S. Patent Application Publication No. US 2003/0027203 A1, published 9 February 2003).

Regarding claim 1, Fields teaches a device in the form of a tip wherein nucleic acids bind to a porous material within a tip (Figures 8-9 and paragraphs 0067-0068). The tip is a tubular housing having a proximal end and a distal end defining an internal flow passageway (Figures 8-9). The housing comprises flow through support material 73 provided therein to obstruct the internal passageway. The support member is a porous material capable of binding nucleic acids (paragraph 0067), and thus comprises through going channels in accordance with the embodiment described in lines 24-35 on page 6 of the instant specification. Thus, the claim has been given the broadest reasonable interpretation consistent with the teachings of the specification regarding a "channel."

In addition, as noted above, it is noted that the phrase "suitable for allowing" clearly indicates that the recitation of "an interaction between target and probe molecules" refers to an intended use of the claimed device, and does not actually require target or probe molecules. As also noted above, apparatus claims cover what a device *is*, not what a device *does*." Therefore, the various uses recited in claim 1 (e.g., allowing an interaction between target and probe molecules) fail to define additional

structural elements of the claimed device. Because Fields teach the structural elements of the claim, the claim is anticipated by Fields.

Regarding claim 3, Fields teaches the device of claim 1, wherein the support member is provided at or near the distal end of the housing (Figure 8). It is noted that the specification does not teach a limiting definition of what is encompassed by the term "near" the distal end. Thus, the claim has been given the broadest reasonable interpretation consistent with the teachings of the specification regarding a “near the distal end.”

Regarding claim 7, Fields teaches the device of claim 1, wherein the plane of the support member extends substantially perpendicular with the longitudinal axis of the housing (Figure 8).

Regarding claim 8, Fields teaches the device of claim 1, wherein the support member spans the bore of the housing; namely, the support member is placed entirely across the opening of tubular housing (Figure 8); thus, the support member is at the end of the housing.

Regarding claim 9, Fields teaches an apparatus having a handling station comprising a handling device; namely, an automated apparatus comprising a handling station comprising a handling device in the form of a robotic pipettor that transports pipette tips (paragraph 0065). The pipettor aspirates and dispenses fluids in the tip (paragraph 0065), and is thus a handling station comprising a handling device in accordance with the embodiment described on page 14 of the instant specification. The apparatus further comprises a robotic translation system for moving the handling station

(i.e., pipette tips) in the form of a robotic arm (Figure 7 and paragraph 0065), which is a "means for transporting" in accordance with the embodiment of a means for transporting described on page 18 of the instant specification. The apparatus of Fields also comprises an incubation section in the form of a region of the device that comprises a heating block, which is a, incubation device for incubating the sample because the specification contains no limiting definition of an incubation section comprising an incubation device. Fields further teaches the apparatus comprises an analysis section comprising a detection assembly in the form of a fluorescence detector (claim 20 of ), which is in accordance with the embodiment of a "detection means" presented on pages 16-17 of the instant specification. Thus, the claim has been given the broadest reasonable interpretation consistent with the teachings of the specification regarding a "handling station" a "handling device" a "means for transporting," and "incubation section comprising an incubation device," and "an analysis section comprising a detection device."

Fields also teaches the use of a tip wherein nucleic acids bind to a porous material within a tip (Figures 8-9 and paragraphs 0067-0068). The tip is a tubular housing having a proximal end and a distal end defining an internal flow passageway (Figures 8-9). The housing comprises flow through support material 73 provided therein to obstruct the internal passageway. The support member is a porous material capable of binding nucleic acids (paragraph 0067), and thus comprises through going channels in accordance with the embodiment described in lines 24-35 on page 6 of the instant

specification. Thus, the claim has been given the broadest reasonable interpretation consistent with the teachings of the specification regarding a "channel."

In addition, as noted above, it is noted that the phrase "suitable for allowing" clearly indicates that the recitation of "an interaction between target and probe molecules" refers to an intended use of the claimed device, and does not actually require target or probe molecules. As also noted above, apparatus claims cover what a device *is*, not what a device *does*." Therefore, the various uses recited in claim 1 (e.g., allowing an interaction between target and probe molecules) fail to define additional structural elements of the claimed device. Because Fields teach the structural elements of the claim, the claim is anticipated by Fields.

### *Claim Rejections - 35 USC § 103*

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. Claims 1 and 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stimpson (U.S. Patent No. 6,306,664 B1, issued 23 October 2001) in view of van Damme et al (U.S. Patent No. 6,225,131 B1, issued 1 May 2001).

It is noted that this rejection applies to claim 1 to the extent that it is drawn to the embodiments of dependent claims 4-6.

It is noted that claim 4 has been rejected under 35 U.S.C 102(b) as described above in Section 12 and claims 4-5 have been rejected under 35 U.S.C 102(b) as described above in Section 13. However, the claims are also obvious using the alternative interpretation outlined below.

Regarding claims 4-6, Stimpson teaches the device of claim 1 for analyzing an interaction between target and probe molecule in the form of Figure 2D, which comprises a tubular housing in the form of sheath 260 (column 6, line 65-column 7, line 10). The housing further comprises a flow through support member in the form of an array comprising through going channels in the form of interstitial spaces 230 (column 6, lines 45-65) which obstructs the internal passage way of the housing (Figure 2D). The channels are suitable for allowing an interaction between target and probe molecules because probe molecules in the form of binding reagents are impregnated therein (column 6, lines 45-65), wherein the binding reagents are DNA probe molecules (column 9, lines 20-40).

In addition, as noted above, it is noted that the phrase "suitable for allowing" clearly indicates that the recitation of "an interaction between target and probe molecules" refers to an intended use of the claimed device, and does not actually require target or probe molecules. As also noted above, apparatus claims cover what a device *is*, not what a device *does*." Therefore, the various uses recited in claim 1 (e.g., allowing an interaction between target and probe molecules) fail to define additional structural elements of the claimed device. Because the prior art teaches the structural elements of the claim, the claim is obvious over the prior art.

Stimpson does not explicitly teach the support member is a metal oxide (i.e., claim 4) or transparent (i.e., claim 5).

However, van Damme et al teach flow through support members in the form of metal oxide membranes (i.e., claim 4) that are transparent (i.e., claim 5). The channels of the membrane are through going oriented channels that allow flow through the membranes (column 3, lines 25-45), and are oriented perpendicular to the surface of r sample application (claim 1 of van Damme). Van Damme et al also teach the membranes have the added advantage of allowing for assays using various optical techniques that also have advantageous surface chemical properties (column 2, lines 1-20). Thus, van Damme et al teach the known technique of using a flow through support member that is a metal oxide (i.e., claim 4), transparent (i.e., claim 5), and has channels perpendicular to the flow direction (i.e., claim 6).

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the device of Stimpson so that the flow through support member is the transparent metal oxide flow through membrane (i.e., claims 4-5) having the channels perpendicularly oriented to the direction of flow as taught van Damme et al to arrive at the instantly claimed device with a reasonable expectation of success. Orientation of the membrane to allow flow through that is perpendicular to the channels results in placement of the membrane so that the channels extend substantially coaxial with the longitudinal axis of the housing (i.e., claim 6). The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a device having the added advantage of

allowing for assays using various optical techniques that also have advantageous surface chemical properties as explicitly taught by van Damme et al (column 2, lines 1-20). In addition, it would have been obvious to the ordinary artisan that the known technique of using the transparent metal oxide flow through support member having the channel orientation as taught by van Damme et al could have been used as the flow through support member in the device of Stimpson with predictable results because the known technique of using the transparent metal oxide flow through support member having the channel orientation as taught by van Damme et al predictably results in use of a reliable flow through support member.

17. Claims 1-2 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fields (U.S. Patent Application Publication No. US 2003/0027203 A1, published 9 February 2003) in view of Stimpson (U.S. Patent No. 6,306,664 B1, issued 23 October 2001).

It is noted that this rejection applies to claim 1 to the extent that it is drawn to the embodiment of dependent claim 2.

It is also noted that while claim 2 has been rejected under 35 U.S.C 102(b) as described above in Sections 12 and 13 and while claim 9 has been rejected under 35 U.S.C 102(b) as described above in Section 14, the claim is also obvious using the alternative interpretation outlined below.

Regarding claim 2, Fields teaches the device of claim 1 in the form of a tip wherein nucleic acids bind to a porous material within a tip (Figures 8-9 and paragraphs

0067-0068). The tip is a tubular housing having a proximal end and a distal end defining an internal flow passageway (Figures 8-9). The housing comprises flow through support material 73 provided therein to obstruct the internal passageway. The support member is a porous material capable of binding nucleic acids (paragraph 0067), and thus comprises through going channels in accordance with the embodiment described in lines 24-35 on page 6 of the instant specification. Thus, the claim has been given the broadest reasonable interpretation consistent with the teachings of the specification regarding a "channel."

In addition, as noted above, it is noted that the phrase "suitable for allowing" clearly indicates that the recitation of "an interaction between target and probe molecules" refers to an intended use of the claimed device, and does not actually require target or probe molecules. As also noted above, apparatus claims cover what a device *is*, not what a device *does*." Therefore, the various uses recited in claim 1 (e.g., allowing an interaction between target and probe molecules) fail to define additional structural elements of the claimed device. Because the prior art teaches the structural elements of the claim, the claim is obvious over the prior art.

Fields does not explicitly teach the porous material in the tip comprises probe molecules.

However, Stimpson teaches a device for analyzing an interaction between target and probe molecule in the form of Figure 2D, which comprises a tubular housing in the form of sheath 260 (column 6, line 65-column 7, line 10). The housing further comprises a flow through support member, wherein the support member is provided

with probe molecules suitable for interacting with target molecules; namely, the channels comprise probe molecules in the form binding reagents that are impregnated therein (column 6, lines 45-65), wherein the binding reagents are DNA probe molecules (column 9, lines 20-40). Stimpson also teaches the material comprising the DNA probe molecules have the added advantage of allowing the sequence of an unknown target DNA to be determined via sequencing by hybridization (column 1, lines 30-45). Thus, Stimpson teaches the known technique of having a flow through support member comprising DNA probes.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the device as taught by Fields so that flow through support member in the tip further comprises probe molecules as taught by Stimpson to arrive at the instantly claimed device with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in an apparatus having the added advantage of employing a time that has the added advantage of allowing the sequence of an unknown target DNA to be determined via sequencing by hybridization as explicitly taught by Stimpson (column 1, lines 30-45). In addition, it would have been obvious to the ordinary artisan that the known technique of having a flow through support member comprising DNA probes as taught by Stimpson could have been used as the support member in the device of Fields with predictable results because the known technique of having a flow through support member comprising DNA probes as taught by Stimpson predictably results in a reliable tip for nucleic acid assays.

Regarding claim 9, Fields teaches an apparatus having a handling station comprising a handling device; namely, an automated apparatus comprising a handling station comprising a handling device in the form of a robotic pipettor that transports pipette tips (paragraph 0065). The pipettor aspirates and dispenses fluids in the tip (paragraph 0065), and is thus a handling station comprising a handling device in accordance with the embodiment described on page 14 of the instant specification. The apparatus further comprises a robotic translation system for moving the handling station (i.e., pipette tips) in the form of a robotic arm (Figure 7 and paragraph 0065), which is a "means for transporting" in accordance with the embodiment of a means for transporting described on page 18 of the instant specification. The apparatus of Fields also comprises an incubation section in the form of a region of the device that comprises a heating block, which is a, incubation device for incubating the sample because the specification contains no limiting definition of an incubation section comprising an incubation device. Fields further teaches the apparatus comprises an analysis section comprising a detection assembly in the form of a fluorescence detector (claim 20 of ), which is in accordance with the embodiment of a "detection means" presented on pages 16-17 of the instant specification. Thus, the claim has been given the broadest reasonable interpretation consistent with the teachings of the specification regarding a "handling station" a "handling device" a "means for transporting," and "incubation section comprising an incubation device," and "an analysis section comprising a detection device."

Fields also teaches the use of a tip wherein nucleic acids bind to a porous material within a tip (Figures 8-9 and paragraphs 0067-0068). The tip is a tubular housing having a proximal end and a distal end defining an internal flow passageway (Figures 8-9). The housing comprises flow through support material 73 provided therein to obstruct the internal passageway. The support member is a porous material capable of binding nucleic acids (paragraph 0067), and thus comprises through going channels in accordance with the embodiment described in lines 24-35 on page 6 of the instant specification. Thus, the claim has been given the broadest reasonable interpretation consistent with the teachings of the specification regarding a "channel."

Fields does not explicitly teach the porous material in the tip comprises probe molecules (i.e., the device of claim 1 as exemplified in the embodiment of claim 2).

However, Stimpson teaches a device for analyzing an interaction between target and probe molecule in the form of Figure 2D, which comprises a tubular housing in the form of sheath 260 (column 6, line 65-column 7, line 10). The housing further comprises a flow through support member, wherein the support member is provided with probe molecules suitable for interacting with target molecules; namely, the channels comprise probe molecules in the form binding reagents that are impregnated therein (column 6, lines 45-65), wherein the binding reagents are DNA probe molecules (column 9, lines 20-40). Stimpson also teaches the material comprising the DNA probe molecules have the added advantage of allowing the sequence of an unknown target DNA to be determined via sequencing by hybridization (column 1, lines 30-45). Thus,

Stimpson teaches the known technique of having a flow through support member comprising DNA probes.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the apparatus as taught by Fields so that flow through support member in the tip further comprises probe molecules as taught by Stimpson to arrive at the instantly claimed device with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in an apparatus having the added advantage of employing a time that has the added advantage of allowing the sequence of an unknown target DNA to be determined via sequencing by hybridization as explicitly taught by Stimpson (column 1, lines 30-45). In addition, it would have been obvious to the ordinary artisan that the known technique of having a flow through support member comprising DNA probes as taught by Stimpson could have been used as the support member in the apparatus of Fields with predictable results because the known technique of having a flow through support member comprising DNA probes as taught by Stimpson predictably results in a reliable tip for nucleic acid assays.

18. Claims 1 and 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raybuck et al (U.S. Patent No. 5,556,598, issued 17 September 1996) in view of van Damme et al (U.S. Patent No. 6,225,131 B1, issued 1 May 2001).

It is noted that this rejection applies to claim 1 to the extent that it is drawn to the embodiments of dependent claims 4-6.

It is noted that claims 4 and 5 have been rejected under 35 U.S.C 102(b) as described above in Section 13, claims 4 and 6 have been rejected under 35 U.S.C 102(b) as described above in Section 12, and claims 4-6 have been rejected under 35 U.S.C 103(a) as described above in Section 16. However, the claims are also obvious using the alternative interpretation outlined below.

Regarding claims 4-6, Raybuck et al teach a device comprising a tubular housing have a proximal end and a distal end defining an internal flow passageway; namely, Figure 6 shows a tubular housing in the form of pipette tip 10, which is shown having a proximal and distal end (i.e., the ends of the tip; column 8, line 58-column 9, line 55). The housing is further provided with a flow through support member in the form of substrate 17 (column 7, lines 15-30), which obstructs the internal passage way of the housing (Figure 6). Substrate 17 is a membrane that is porous (column 5, lines 30-50), and thus comprises through going channels in accordance with the embodiment described in lines 24-35 on page 6 of the instant specification. Thus, the claim has been given the broadest reasonable interpretation consistent with the teachings of the specification regarding a "channel."

In addition, as noted above, it is noted that the phrase "suitable for allowing" clearly indicates that the recitation of "an interaction between target and probe molecules" refers to an intended use of the claimed device, and does not actually require target or probe molecules. As also noted above, apparatus claims cover what a device *is*, not what a device *does*." Therefore, the various uses recited in claim 1 (e.g., allowing an interaction between target and probe molecules) fail to define additional

structural elements of the claimed device. Because Raybuck et al teach the structural elements of the claim, the claim is anticipated by Raybuck et al.

Raybuck et al does not explicitly teach the support member has channels extending substantially coaxial with the longitudinal axis of the housing (i.e., claim 6).

However, van Damme et al teach flow through support members in the form of metal oxide membranes (i.e., claim 4) that are transparent (i.e., claim 5). The channels of the membrane are through going oriented channels that allow flow through the membranes (column 3, lines 25-45), and are oriented perpendicular to the surface for sample application (claim 1 of van Damme). Van Damme et al also teach the membranes have the added advantage of allowing for assays using various optical techniques that also have advantageous surface chemical properties (column 2, lines 1-20). Thus, van Damme et al teach the known technique of using a flow through support member that is a metal oxide (i.e., claim 4), transparent (i.e., claim 5), and has channels perpendicular to the flow direction (i.e., claim 6).

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the device of Raybuck et al so that the flow through support member is the transparent metal oxide flow through membrane (i.e., claims 4-5) having the channels perpendicularly oriented to the direction of flow as taught van Damme et al to arrive at the instantly claimed device with a reasonable expectation of success. Orientation of the membrane to allow flow through that is perpendicular to the channels results in placement of the membrane so that the channels extend substantially coaxial with the longitudinal axis of the housing

(i.e., claim 6). The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a device having the added advantage of allowing for assays using various optical techniques that also have advantageous surface chemical properties as explicitly taught by van Damme et al (column 2, lines 1-20). In addition, it would have been obvious to the ordinary artisan that the known technique of using the transparent metal oxide flow through support member having the channel orientation as taught by van Damme et al could have been used as the flow through support member in the device of Raybuck et al with predictable results because the known technique of using the transparent metal oxide flow through support member having the channel orientation as taught by van Damme et al predictably results in use of a reliable flow through support member.

19. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fields (U.S. Patent Application Publication No. US 2003/0027203 A1, published 9 February 2003) in view of Raybuck et al (U.S. Patent No. 5,556,598, issued 17 September 1996).

It is noted that claim 9 has been rejected under 35 U.S.C 102(b) as described above in Section 14 and has been rejected under 35 U.S.C 103(a) as described above in Section 17. However, the claim is also obvious using the alternative interpretation outlined below.

Regarding claim 9, Fields teaches an apparatus having a handling station comprising a handling device; namely, an automated apparatus comprising a handling station comprising a handling device in the form of a robotic pipettor that transports

pipette tips (paragraph 0065). The pipettor aspirates and dispenses fluids in the tip (paragraph 0065), and is thus a handling station comprising a handling device in accordance with the embodiment described on page 14 of the instant specification. The apparatus further comprises a robotic translation system for moving the handling station (i.e., pipette tips) in the form of a robotic arm (Figure 7 and paragraph 0065), which is a "means for transporting" in accordance with the embodiment of a means for transporting described on page 18 of the instant specification. The apparatus of Fields also comprises an incubation section in the form of a region of the device that comprises a heating block, which is a, incubation device for incubating the sample because the specification contains no limiting definition of an incubation section comprising an incubation device. Fields further teaches the apparatus comprises an analysis section comprising a detection assembly in the form of a fluorescence detector (claim 20 of ), which is in accordance with the embodiment of a "detection means" presented on pages 16-17 of the instant specification. Thus, the claim has been given the broadest reasonable interpretation consistent with the teachings of the specification regarding a "handling station" a "handling device" a "means for transporting," and "incubation section comprising an incubation device," and "an analysis section comprising a detection device."

While Fields teaches the use of a hybridization tube (paragraph 0063) and the binding of nucleic acids to porous material within a tip (Figures 8-9 and paragraphs 0067-0068), Fields does not explicitly teach the tip is the device of claim1.

However, Raybuck et al teach the device of claim 1 comprising a tubular housing have a proximal end and a distal end defining an internal flow passageway; namely, Figure 6 shows a tubular housing in the form of pipette tip 10, which is shown having a proximal and distal end (i.e., the ends of the tip; column 8, line 58-column 9, line 55). The housing is further provided with a flow through support member in the form of substrate 17 (column 7, lines 15-30), which obstructs the internal passage way of the housing (Figure 6). Substrate 17 is a membrane that is porous (column 5, lines 30-50), and thus comprises through going channels in accordance with the embodiment described in lines 24-35 on page 6 of the instant specification. Thus, the claim has been given the broadest reasonable interpretation consistent with the teachings of the specification regarding a "channel."

In addition, as noted above, it is noted that the phrase "suitable for allowing" clearly indicates that the recitation of "an interaction between target and probe molecules" refers to an intended use of the claimed device, and does not actually require target or probe molecules. As also noted above, apparatus claims cover what a device *is*, not what a device *does*." Therefore, the various uses recited in claim 1 (e.g., allowing an interaction between target and probe molecules) fail to define additional structural elements of the claimed device. Because the prior art teaches the structural elements of the claim, the claim is obvious over the prior art.

Raybuck et al also teach device has the added advantage of allowing further visualization of bound entities, efficient elution, and culturing of cellular entities on the

membrane if desired (column 7, lines 35-45). Thus, Raybuck et al teach the known technique of providing a device in accordance with claim 1.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the apparatus as taught by Raybuck et al so that the tip having the porous material is the device of claim 1 as taught by Raybuck et al to arrive at the instantly claimed apparatus with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in an apparatus having the added advantage of employing a time that has the added advantage of allowing further visualization of bound entities, efficient elution, and culturing of cellular entities on the membrane if desired as explicitly taught by Raybuck et al (column 7, lines 35-45). In addition, it would have been obvious to the ordinary artisan that the known technique of using the tip of Raybuck et al could have been used as the tip in the apparatus of Fields with predictable results because the known technique of using the tip of Raybuck et al predictably results in a reliable tip for nucleic acid assays.

20. Claims 1 and 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fields (U.S. Patent Application Publication No. US 2003/0027203 A1, published 9 February 2003) in view of van Damme et al (U.S. Patent No. 6,225,131 B1, issued 1 May 2001).

It is noted the claims 4-5 are rejected under 35 U.S.C. 102(b) as described above in Section 13, claims 4 and 6 are under 35 U.S.C. 102(b) as described above in Section

12, and claims 4-6 are rejected under 35 U.S.C. 103(a) as described above in Sections 16 and 18. However, the claims are also obvious using the alternative interpretation outlined below.

Regarding claim 4-6, Fields teaches the device of claim 1 as described above in Sections 14 and 17.

Fields does not explicitly teach the support member has channels extending substantially coaxial with the longitudinal axis of the housing (i.e., claim 6).

However, van Damme et al teach flow through support members in the form of metal oxide membranes (i.e., claim 4) that are transparent (i.e., claim 5). The channels of the membrane are through going oriented channels that allow flow through the membranes (column 3, lines 25-45), and are oriented perpendicular to the surface of r sample application (claim 1 of van Damme). Van Damme et al also teach the membranes have the added advantage of allowing for assays using various optical techniques that also have advantageous surface chemical properties (column 2, lines 1-20). Thus, van Damme et al teach the known technique of using a flow through support member that is a metal oxide (i.e., claim 4), transparent (i.e., claim 5), and has channels perpendicular to the flow direction (i.e., claim 6).

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the device of Fields so that the flow through support member is the transparent metal oxide flow through membrane (i.e., claims 4-5) having the channels perpendicularly oriented to the direction of flow as taught van Damme et al to arrive at the instantly claimed device with a reasonable

expectation of success. Orientation of the membrane to allow flow through that is perpendicular to the channels results in placement of the membrane so that the channels extend substantially coaxial with the longitudinal axis of the housing (i.e., claim 6). The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a device having the added advantage of allowing for assays using various optical techniques that also have advantageous surface chemical properties as explicitly taught by van Damme et al (column 2, lines 1-20). In addition, it would have been obvious to the ordinary artisan that the known technique of using the transparent metal oxide flow through support member having the channel orientation as taught by van Damme et al could have been used as the flow through support member in the device of Fields with predictable results because the known technique of using the transparent metal oxide flow through support member having the channel orientation as taught by van Damme et al predictably results in use of a reliable flow through support member.

***Double Patenting***

21. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

22. Claims 1-4 and 6-8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 51-53 of copending Application No. 11/662,397 in view of Stimpson (U.S. Patent No. 6,306,664 B1, issued 23 October 2001). Both sets of claims are drawn to device comprising a flow through support member (i.e., a solid porous support) having channels that is part of a device. The additional limitations of the '397 claims are encompassed by the open claim language "comprising" found in the instant claims.

The '397 claims do not require the support member of the device be in a tubular housing.

However, Stimpson teaches a device for analyzing an interaction between target and probe molecule in the form of Figure 2D, which comprises a tubular housing in the form of sheath 260 (column 6, line 65-column 7, line 10). The housing further comprises a flow through support member, wherein the support member is provided with probe molecules suitable for interacting with target molecules; namely, the channels comprise probe molecules in the form binding reagents that are impregnated therein (column 6, lines 45-65), wherein the binding reagents are DNA probe molecules (column 9, lines 20-40).

Stimpson also teaches the device comprises a support member is provided with probe molecules suitable for interacting with target molecules; namely, the channels comprise probe molecules in the form binding reagents that are impregnated therein (column 6, lines 45-65), wherein the binding reagents are DNA probe molecules (i.e., claim 2; column 9, lines 20-40).

Stimpson further teaches the device comprises a support member that provided at the distal end of the housing; namely, the support member is places entirely withing the tubular housing (Figures 2D-E); thus, the support member is at the end of the housing (i.e., claim 3).

Stimpson teaches the device wherein the support member (i.e., porous matrix) is an organic polymer; namely, polypropylene (i.e., claim 4; column 3, lines 48-65).

Stimpson further teaches the device, wherein the channels extend substantially coaxial with the longitudinal axis of the housing (i.e., claim 6; Figures 1B and C).

Stimpson teaches the device wherein the plane of the support member extends substantially perpendicular with the longitudinal axis of the housing (i.e., claim 7; Figures 1B and C).

Stimpson teaches the device wherein the support member spans the bore of the housing; namely, the support member is placed entirely within the tubular housing (Figures 2D-E); thus, the support member is at the end of the housing (i.e., claim 8).

Stimpson also teaches the material comprising the DNA probe molecules have the added advantage of allowing the sequence of an unknown target DNA to be determined via sequencing by hybridization (column 1, lines 30-45). Thus, Stimpson

teaches the known technique of having a flow through support member comprising DNA probes.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the apparatus of the '397 claims so that flow through support member is in a tip and further comprises additional limitations as taught by Stimpson to arrive at the instantly claimed device with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in an apparatus having the added advantage of employing a time that has the added advantage of allowing the sequence of an unknown target DNA to be determined via sequencing by hybridization as explicitly taught by Stimpson (column 1, lines 30-45). In addition, it would have been obvious to the ordinary artisan that the known technique of having a flow through support member in a tip as taught by Stimpson could have been applied to the '397 claims with predictable results because the known technique of having a flow through support member in a tip as taught by Stimpson predictably results in a reliable tip for nucleic acid assays.

This is a provisional obviousness-type double patenting rejection.

***Conclusion***

23. No claim is allowed.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert T. Crow whose telephone number is (571)272-

1113. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert T. Crow/
Examiner, Art Unit 1634

Robert T. Crow
Examiner
Art Unit 1634